MR#328015

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8EHQ-10-18016

June 23, 2010 **This Report CONTAINS Confidential Business Information**

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CONFIRMATION OF RECEIPT REQUESTED

Document Control Office (7407M)
U.S. Environmental Protection Agency
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

SUBJECT: TSCA 8(e) SUBMISSION

Dear Sir or Madam,

(" ") is submitting certain data which we believe to be reportable under TSCA 8(e). The information concerns , an experimental sulfone insecticide compound. is identified by IUPAC as:

The CAS number assigned for this compound is not yet assigned.

has not imported for R&D on behalf of (" ") but plans to do so in the future.

The following report concerning has been submitted to your agency:
(Document Control Number 8EHQ -08-17252) was submitted to your agency on September 2, 2008.

recently learned of new toxicological effects in a one week oral toxicity study in rats. An outline of the study follows:

One Month Study
[CONTENTS]
was exposed to BrlHan: WIST@Jcl(GALAS) rats (6 animals/dose/sex) by feeding the diet containing the test substance at the concentration of 200,500,1500 and 3000 ppm for one month. Muscular rigidity, increase of spontaneous activity, degeneration/necrosis or fibrosis of myocardium and atrophy of thymus or uterus were observed. No-observed-adverse-effect level (NOAEL) was as follow: Male; 200ppm (20.4 mg/kg/day), Female; 200ppm (20.2 mg/kg/day)
We judged that this information needed to be reported based on neurotoxicological effects (muscular rigidity and increase of spontaneous activity) and the histopathological finding suggesting severe functional effect from test substance (degeneration/necrosis or fibrosis of myocardium and atrophy of thymus or uterus) observed and because the NOAEL was lower than 200 mg/kg/day.

Company Sanitized

[COMMENTS]
Test substance: (Purity; 99.4 %, Lot No.:251-090826-1)
Animals: Male and Female, BrlHan: WIST@Jcl rats (SPF),
5 weeks old at administration
Treatment periods: One month
Route of administration: Test substance was administered in diet.
Dose level: 0*、200、500、1500、3000 ppm diet, 6 animals/dose/sex (*: basal diet only)
Examination items: clinical signs, functional observational battery,
locomotor activity, body weights, body weight gains, food consumption,
ophthalmology, urinalysis, hematology, blood biochemistry, absolute organ
weights, relative organ weights, gross pathology, histopathology, electron
microscopic examination
Other findings: Treatment related toxic effects were observed in clinical sings,
locomotor activity, the body weights, body weight gains, food consumption,
hematology, blood biochemistry, absolute organ weights, relative organ weights,
gross pathology, histopathology or electron microscopic examination in both
sexes at more than 500ppm. Death was observed in one male at 3000ppm.

One Week Study
[CONTENTS]
was exposed to BrlHan: WIST@Jcl(GALAS) rats (4 animals/dose/sex) by feeding the diet containing the test substance at the concentration of 1500, 5000, 10000 and 20000 ppm for one week. Small of thymus or seminal vesicle were observed.
No-observed-adverse-effect level (NOAEL) was as follow:
Male; Lower than 1500ppm (145.2 mg/kg/day), Female; Lower than 1500ppm (132.5 mg/kg/day)
We judged that this information needed to be reported based on the histopathological finding suggesting severe functional effect from test substance (small of thymus or seminal vesicle) and that the NOAEL was lower than 200 mg/kg/day.
[COMMENTS]
METHOD:
Test substance: (Purity; 99.4 %, Lot No.:251-090826-1)
Animals: Male and Female, BrlHan: WIST@Jcl rats (SPF),
5 weeks old at administration
Treatment periods: One week
Route of administration: Test substance was administered in diet.
Dose level: 0*、1500、5000、10000、20000 ppm diet,
4 animals/dose/sex (*: basal diet only)
Examination items: clinical signs, body weights, body weight gains, food consumption,
ophthalmology, hematology, blood biochemistry, absolute organ weights,
relative organ weights, gross pathology
Other findings: Treatment related toxic effects were observed in the body weights,
body weight gains, food consumption, hematology, blood biochemistry,

absolute organ weights, relative organ weights or gross pathology in both sexes at more than 1500ppm.

Substantiation of CBI Claims

We wish to substantiate 's claims that certain information in this letter be treated as Confidential Business Information ('CBI'). All information which has been deleted from the sanitized version of this letter should be treated as CBI. In substantiation of this CBI claim, wishes to protect its confidential business plan for the commercial development of this compound. Disclosure of this information would harm 's efforts to commercialize this compound. Please refer to the attached letter of September 2, 2008 to Mr. Edward Gross regarding substantiation of CBI claims.

If there are any questions on this submission please feel free to contact me at ( ).

Yours sincerely,

Encl.
cc: